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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,099	09/12/2003	Andrew Vaillant	029849-0203	6577

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,099	VAILLANT ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *3-13,21-25 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,14-20 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Final Office Action is in response to the After-Non-Final amendment filed on 8 June 2006. Claims 1-38 are pending, of which claims 3-13, 21-25, and 33-38 are withdrawn from consideration and claims 1, 2, 14-20, and 26-32 are under examination.

Specification

The objection to the disclosure **is withdrawn** in view of the Applicants' amendment.

Double Patenting

The Examiner notes with appreciation that Applicants filed a terminal disclaimer. The nonstatutory double patenting rejection of claims 1, 2, 14-20, and 26-32 as being unpatentable over claims 1-3, 5, 7-10, 12-14, 18-20, 28, and 29 of copending Application No. 11/661,403 is held in abeyance until the terminal disclaimer is approved.

Claim Rejections - 35 USC § 112

The rejection of claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite **is withdrawn** in view of Applicants' amendment.

The rejection of claims 1, 2, 14-20 and 26-32 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope with the claims **is maintained** for reasons of record.

Applicants argue that USPTO is not entitled to substitute itself to the FDA in order to evaluate the clinical relevance of the present invention. Relying on a

Declaration from Dr. Jean-Marc Juteau, Applicants allege that the present invention has clinical relevance and that the *in vitro* results disclosed in the present application do not diverge from *in vivo* response. Applicants' arguments have been fully considered and found unpersuasive.

The Juteau declaration under 37 CFR 1.132 filed on 8 June 2006 is insufficient to overcome the rejection of claims 1, 2, 14-20 and 26-32 based upon insufficiency of disclosure under 35 U.S.C. §112, first paragraph as set forth in the last Office action because the facts presented are not germane to the rejection at issue and the scope of showing is not commensurate in scope with the claims. The declaration presents an SIV model in non-human primates and an FLV disease mice model, which is nonanalogous to the claimed method of prophylaxis and treatment of HIV in humans. FLV is an entirely different virus from HIV in the claimed invention. SIV is known in the art to be not predictive of the HIV in humans because the monkey body may react differently to the an HIV vaccine than the human body. For example, the vaccine candidate developed by Merck in 2001, based on promising immunogenicity studies in macaques, showed only marginal immunogenicity in human trials (Jefferys, 2005, page 22). Therefore, the examples of the declaration are not representative of the whole scope of the claimed subject matter.

Regardless of the FDA requirement, the clinical relevance is important to demonstrate the correlation between *in vitro* data and *in vivo* results in humans. The art of HIV gene therapy is highly unpredictable. Teachings in the art show no correlation between experimental data in animal models and clinical data in human trials. DNA

vaccine constructs have proven immunogenic in mice and monkey studies, but data from human trials showed only a minority of recipients displaying low-level T-cell responses to the vaccines. Humans are much larger than the animals used in preclinical studies, and the dose of DNA vaccine that can be delivered is limited by the fact that DNA becomes difficult to inject at doses above 5 mg (Jefferys, 2005, page 21-24). Thus, the disclosure does not remotely relate to medical treatment and prophylaxis of HIV, especially, in humans. Based on the art teaching the ineffectiveness of HIV vaccines and the analysis of the evidence as a whole by considering the factors of *In re Wand*, the instant claims are not enabled for the method for the prophylaxis or treatment of a HIV infection in a human.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 14-17, 28, and 30-32 under 35 U.S.C. §102(b) as being anticipated by Andreola *et al.* (2001) **is withdrawn** in view of the addition of claim limitation "sequence-independent" to anti-HIV activity.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 14-16, 18-20, 26, and 28-31 under 35 U.S.C. §103 (a) as being obvious over Mashall *et al.* (1992, "Marshall") in view of Mergny *et al.* (1998, "Mergny") and Matsukura *et al.* (1987, "Matsukura") **is withdrawn** in view of the addition of the limitation "30 nucleotides" to the length of the oligonucleotides.

New Claim Objections

Claim 1 is objected to because of a grammatical error: the word after "wherein said oligonucleotide" should be "has" instead of "have." Appropriate correction is required.

New Claim Rejections - 35 USC § 112

Claims 1, 2, 14-20, and 26-32 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.* Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." M.P.E.P. §2163.

For a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

In the instant case, the claims are drawn to a method comprising administering at least one pharmacologically acceptable oligonucleotide at least 30 nucleotides in length, wherein said oligonucleotide has an anti-HIV activity and wherein the anti-HIV activity of said oligonucleotide occurs principally by a sequence independent mode of action. The newly amended limitation "sequence independent mode of action" encompasses all possible targets related to HIV, including any part of the HIV, e.g. Env, Gag, Pol, etc. Since there is no sequence requirement for the oligonucleotide, there is no structure description. Therefore, the claims are drawn to a genus of nucleic acids that is defined only by functional reduction of anti-HIV activity.

The specification only provides description for 45 oligonucleotides, of which only 26 have nucleotide sequence identity (p. 104-106, Table 1). The remaining 19 oligonucleotides in Table 1 disclose only the length of the oligonucleotide. Therefore, 26 sequences do not constitute a representative number of species to adequately describe such a broad genus of olignonucleotides. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the oligonucleotides beyond those disclosed in the examples in the specification. Moreover, the

specification lacks sufficient variety of species to reflect this highly variable genus. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (page 1116).

As discussed above, the skilled artisan cannot envision the detailed chemical structure and function of the encompassed genus of undefined nucleotide and/or peptide fragments. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of cloning or isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483, claims directed to mammalian FGF's were found to be unpatentable due to lack of written descriptions for that broad class.

Therefore, claims 1, 2, 14-20, and 26-32 do not meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (page 1115).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
16 Aug 2006

8/16/06